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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/626,218

07/22/2003

Lars Tommy Westbye

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09/06/2006

ORRICK, HERRINGTON & SUTCLIFFE, LLP  
IP PROSECUTION DEPARTMENT  
4 PARK PLAZA  
SUITE 1600  
IRVINE, CA 92614-2558

EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/626,218

Applicant(s)

WESTBYE ET AL.

Examiner

Catherine N. Witczak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/6/05; 4/15/04; 10/20/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

~~~~~ 8/23/00

## DETAILED ACTION

### *Specification*

The abstract of the disclosure is objected to because it exceeds the 150 word limit. Correction is required. See MPEP § 608.01(b).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stewart, Sr (US 6,230,530) as modified by Doyle et al (WO 01/85239) in further view of Holman et al (US 5,104,380).

Stewart discloses an automatic injection system configured to house a medical cartridge comprising driver system comprising a driver (16), a drive bias member comprising an inner (120) and outer (110) bias members connected by a coupling (126), an indicator (82) to indicate dose injection, a distal housing (40) attachable to a proximal housing (12) and coupled with the drive system, the distal housing having a sleeve (88) having a detent (92) and a sleeve bias member (94) and a ring (70) coupled with the distal housing and slideably coupled to the sleeve.

Stewart discloses the claimed invention except for the needle guard. Doyle et al teach that it is known to use a needle guard comprising a cartridge housing (20) coupled with a release mechanism (74) and configured to house a medical cartridge (90) comprising a needle (95), a plunger (98) and a carrier (92); a shield (60) coupled with the cartridge housing and the release

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mechanism, which comprises a first cooperating catch (76) formed in the shield, a second cooperating catch (48) formed in the cartridge housing, and a latch member (74), and a bias member (80) in contact with the shield and the cartridge housing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stewart with a needle guard as taught by Doyle et al, since such a modification would provide shielding on the needle tip, preventing exposure upon removal of the needle from the injector.

Stewart discloses the claimed invention expect for a depth adjuster. Holman et al disclose in Figure 1 that it is known to use a depth adjuster. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Stewart and modified by Doyle, since such a modification would allow for control of the injection penetration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cw



9/1/06

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

